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10/568,418	04/26/2006	Shirou Sawa	2006_0177A	7556

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EXAMINER	
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ART UNIT	PAPER NUMBER
1612	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/568,418	SAWA ET AL.	
	Examiner	Art Unit	
	GIGI HUANG	1612	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 April 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☐ Claim(s) *1,3,5-7 and 9-11* is/are pending in the application.

4a) Of the above claim(s) *6,7 and 9* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3,5,10 and 11* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *3/6/2008, 3/18/2009*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of Application

1. The response filed April 14, 2009 has been received, entered and carefully considered. The response affects the instant application accordingly:

   a. Claim 1 has have been amended.

   b. Claim 8 has been cancelled.

2. Claims 1, 3, 5-7, 9-11 are pending in the case.

3. Due to the amendment, the organic amine was expanded to include alkanolamine and piperazine.

4. Claims 1, 3, 5, 10-11 are present for examination.

5. Claim 5 has been included due to the 112 2nd issue as addressed below, pending clarification of the terms.

6. The text of those sections of title 35.U.S. Code not included in this action can be found in the prior Office action.

7. All grounds not addressed in the action are withdrawn or moot.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claims 1,3, and 5 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. See MPEP § 2173.05(c). Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949). In the present instance, claim 1 and 5 recites the broad recitation "amino acid", and the claim also recites "aminoalkylsulfonic acid" which is the narrower statement of the range/limitation. Aminoalkylsulfonic acid has amino and acid groups whereby it is reads on the broader recitation of amino acid (e.g. taurine is considered an amino acid in the art). It does not allow one of skill in the art to ascertain the metes and bounds of the claims. For purposes of prosecution any compound fulfilling either the narrow or broad term applies.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

9. Claims 1 and 3 are rejected under 35 U.S.C. 102(b) as being anticipated by Ogawa et al (U.S. Pat. No. 4910225).

Ogawa teaches a method of treating inflammatory eye disease with an ophthalmic composition comprised of a benzoylphenylacetic acid or its salt or the hydrate, in one or more compound mixtures, buffers, and optionally with an isotonizing agent, a preservative, a chelating agent, and a thickening agent. The concentration of the active ingredient may range from about 0.001% to about 10%, preferably in the range of 0.01 to about 5%. Ogawa teaches the composition to be useful in treating inflammatory ophthalmic conditions such as uveitis and conjunctivitis. The composition can be in the form of a solution (aqueous and non-aqueous) and be administered as eye drops, ointments and any other known compositions for topical administration to the eye. The eye drops are to be administered one to several drops per dose in a frequency of once to four times a day according to the clinical condition. The dosage may be adjusted according to symptoms.

The example teach compositions consisting essentially of the specific drug sodium 3-(4-bromobenzoyl) 2-aminophenylacetate/monohydrate at 0.1% with sodium edentate (EDTA) at a sufficient quantity (generally 0.02%), and other excipients such as buffers. The EDTA is an organic amine known as ethylenediaminetetraacetic acid which is an amino acid. The recitation of the maintenance of bromfenac in the humor is a recitation of intended effect which is inherently met when the components present in the composition (e.g. bromfenac, the organic amine) and the mode of administration are

met as the results are the same. (Abstract, Col. 1, lines 33-38, 60-68, Col. 2, lines 1-36, 45-68, Col. 3, lines 30-54, Col. 4, lines 20-68, Col.5, lines 1-15-23, Col.6, lines 20-48, 53-68, Col.7, lines 1-68, Col8, lines 1-20, 25-68, Col.9, Example 1-2, Col.10, Example 6-7).

All the critical elements are taught by the cited reference and thus the claims are anticipated.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

10. Claim 5 and 9-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ogawa et al (U.S. Pat. No. 4910225) as applied to claims 1 and 3, in view of Kessler (U.S. Pat.5849291).

The teachings of Ogawa are addressed above. Ogawa also teaches aqueous solutions in the examples consisting essentially of bromfenac and buffers such as boric acid-borax (sodium borate) and sodium monohydrogen phosphate-sodium dihydrogen phosphate.

Owaga et al. does not expressly teach the incorporation of an aminoalkylsulfonic acid, piperazine, or its range.

Kessler teaches known buffers for ophthalmic compositions such as Na2HPO4-NaH2PO4 (sodium monohydrogen phosphate-sodium dihydrogen phosphate), boric

acid-sodium borate, and Good Buffers including MES, ACES, PIPES (in the class of aminoalkyl sulfonic acid compounds, see Penny) as functional equivalents (Col. 7 line 3-16).

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to substitute a Good buffer such as ACES or PIPES, as suggested by Kessler, and produce the instant invention. It would have been obvious to one of skill in the art to substitute one known buffer (boric acid-borax, sodium monohydrogen phosphate-sodium dihydrogen phosphate) for another known buffer such as ACES or PIPES as they are functional equivalents when motivated by pricing, availability, or desired properties of the pH range of the final product. When the buffer ACES/PIPES in the exemplified compositions, the component is at about 1.0% meeting the claims.

One of ordinary skill in the art would have been motivated to do this as it is desirable for manufacturers to have analogous choices to substitute the buffer when motivated by pricing, availability, or desired pH range and stability for the final product.

11. Claims 5, 10-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ogawa et al (U.S. Pat. No. 4910225) as applied to claims 1 and 3 above, in view of Kato (U.S. Pat. 5945121).

The teachings of Ogawa are addressed above.

Owaga et al. does not expressly teach the incorporation of taurine (aminoethylsulfonic acid) in the composition.

Kato et al. teaches that taurine is effective in the treatment of dry eye and other inflammatory conditions. Kato teaches that taurine when delivered to the eye is effective preferably in the range of 0.5 to 3.0% by weight for the treatment of dry eye (Col. 1, lines 10-48).

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to incorporate taurine, as suggested by Kato et al., and produce the instant invention. It would have been obvious to one of skill in the art to incorporate taurine to the composition for treating an inflammatory condition such as dry eye, as it is obvious to combine two compositions each of which is taught by prior art to be useful for same purpose in order to form third composition that is to be used for very same purpose; the idea of combining them flows logically from their having been individually taught in prior art.

One of ordinary skill in the art would have been motivated to do this as it is routine in the art to have combine of drugs for the same purpose to provide a more effective composition to treat the condition desired. Owaga teaches explicitly, the incorporation of other active agents (Col. 4, lines 16-20) and Kato teaches that taurine is compatible with anti-inflammatories.

12. Claim 1, 3, 5-7, 9-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Miyagi et al. (U.S. Pat. 6281224) in view of Ogawa et al. (Effects of bromfenac sodium, nonsteroidal anti-inflammatory drug, on acute ocular inflammation).

Miyagi et al. teaches an ophthalmic solution with 0.01 to 0.5wt.% of pranoprofen and 0.1 to 5.0wt.% of an organic amine to treat an inflammatory disease of the eye. The

conditions include those in the extraocular area and the anterior segment of the eye such as keratoconjunctivitis. Pranoprofen is a non-steroidal anti-inflammatory drug and the preferred organic amine include alkanolamines such as tromethamine, monoethanolamine, sulfoalkylpiperazine such as HEPES and PIPES, and sulfoalkylalkylenediamines such as N,N'-bis(3-sulfopropyl)ethylenediamine which structurally can be viewed as within the class of aminoalkylsulfonic acids. There are examples exemplifying the composition with tromethanime and HEPES with pranoprofen at various concentrations.

Miyagi et al. does not expressly teach a composition with bromfenac as the active agent.

Miyagi et al. does however teach the composition of a NSAID pranoprofen with the organic amine as addressed above.

Ogawa et al. (Effects of bromfenac...) teaches that bromfenac was more potent than pranoprofen in inhibiting ocular inflammation and may be useful in conjunctivitis and inflammation.

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to utilize bromfenac, as suggested by Ogawa et al. (Effects of bromfenac...), and produce the instant invention. It would have been obvious to one of skill in the art to substitute a more potent NSAIDS such as bromfenac for pranoprofen for the treatment of ocular inflammation such as conjunctivitis as bromfenac would be more effective that pranoprofen.

One of ordinary skill in the art would have been motivated to do this as it is desirable to utilize a more potent and effective drug for the composition to attain a greater therapeutic result and improved treatment.

Response to Arguments

13. In regards to the IDS of March 6, 2008 has been considered and included with the action. It is noted that the IDS cites the date to be January 31, 2008 and the arguments appear to have a typographical error as it addresses the issue date to be July 31, 2008 which is after the IDS date, but the date on the supplemental report is February 7, 2008 which has been corrected on the IDS. If there is an additional report with dates in January or July of 2008 is to be considered, submission of these reports is requested.

14. Claims 1, 3, 8 are rejected under 35 U.S.C. 102(b) as being anticipated by Ogawa et al. (U.S. Pat. No. 4910225).

Claim 8 is cancelled, the rejection is moot.

Applicant's arguments filed 3/12/2009 and 4/3/2009 have been fully considered but they are not persuasive. Applicant asserts that Ogawa does not anticipate the claims as amended. As addressed above, the claims are subject to 112 2nd issues whereby the claims are currently still anticipated by the art. It is noted while the compounds ethylenediamine and ethylenediaminetetraacetic acid would not be anticipatory but would be obvious as addressed by Applicant, the claims previously were directed to the class of ethylenediamines as reflected by the generic terms such as the piperazine and amino acid whereby ethylenediaminetetraacetic acid (EDTA)

would be in the class of ethylenediamines. The issue is moot as the terms are no longer presented in the claims.

Accordingly, the rejection is maintained.

15. Claims 10-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ogawa et al. (U.S. Pat. No. 4910225) as applied to claims 1, 3, and 8 above, in view of Kato (U.S. Pat. 5945121).

Applicant's arguments filed 3/12/2009 and 4/3/2009 have been fully considered but they are not persuasive. Applicant's argument with respect to the liposome carrier is not persuasive as it is not commensurate to the rejection presented for Ogawa et al. in view of Kato. The rejection is to the incorporation of taurine and bromfenac for the treatment of ophthalmic inflammatory conditions such as dry eye/conjunctivitis as Owaga teaches the bromfenac composition to be useful for ophthalmic inflammatory conditions and Kato teaches taurine to be useful for ophthalmic inflammatory conditions such as dry eye, in the preferred range of 0.5 to 3%. It is obvious to combine two agents known for the same purpose to arrive to a composition with those agents for the same purpose.

Accordingly, the rejection is maintained.

16. In regards to the amendment of "consisting essentially of" into the claims as excluding a liposome carrier, the argument is not persuasive as the recitation excludes agents that materially affect the composition such as other active agents (e.g. antibiotics, other NSAIDS, anti-fungals) but not excipients such as buffers, solubility agents, chelating agents, or emulsifiers. The recitation as a result would not exclude

emulsifiers or liposomes in an aqueous carrier. The argument however is not commensurate to the rejection presented for Ogawa et al. in view of Kato as the rejection is to the incorporation of taurine and bromfenac for the treatment of ophthalmic inflammatory conditions such as dry eye/conjunctivitis as it is obvious to combine two agents known for the same purpose.

Conclusion

17. Claims 1, 3, 5, 10-11 are rejected.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to GIGI HUANG whose telephone number is (571)272-9073. The examiner can normally be reached on Monday-Thursday 8:30AM-6:00PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Fredrick Krass can be reached on 571-272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

GH
/Zohreh A Fay/
Primary Examiner, Art Unit 1612